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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/839,658 04/19/2001 Allan Bradley 11635-004001/ OTA 9914 00-51 **EXAMINER** 10/18/2005 7590 SONIA K. GUTERMAN, ESQ. STRZELECKA, TERESA E MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C **ART UNIT** PAPER NUMBER ONE FINANCIAL CENTER BOSTON, MA 02111 1637

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	
Office Action Summary		09/839,658	BRADLEY ET AL.	
		Examiner	Art Unit	
		Teresa E. Strzelecka	1637	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
WHI(- Exte after - If NO - Faild Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory period we are to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).	
Status				
1)[\implies]	Responsive to communication(s) filed on 02 A	ugust 2005		
,		action is non-final.		
3)	Since this application is in condition for allowar		secution as to the merits is	
•	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.			
Disposit	ion of Claims			
4)🖂	Claim(s) 1-14,17 and 67-72 is/are pending in the application.			
	4a) Of the above claim(s) is/are withdrawn from consideration.			
5)	Claim(s) is/are allowed.			
6)⊠	Claim(s) <u>1-14,17 and 67-72</u> is/are rejected.			
7))☐ Claim(s) is/are objected to.			
8)	8) Claim(s) are subject to restriction and/or election requirement.			
Applicat	ion Papers			
9) The specification is objected to by the Examiner.				
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority (ınder 35 U.S.C. § 119			
- 1	12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:			
	1. Certified copies of the priority documents have been received.			
	2. Certified copies of the priority documents have been received in Application No			
	3. Copies of the certified copies of the priority documents have been received in this National Stage			
application from the International Bureau (PCT Rule 17.2(a)).				
* See the attached detailed Office action for a list of the certified copies not received.				
			·	
Attachment(s)				
	e of References Cited (PTO-892)	4) Interview Summary	•	
	e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P	ate atent Application (PTO-152)	
Paper No(s)/Mail Date 6) Other:				

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

- A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 1. CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 2, 2005 has been entered.
- 2. Claims 1-14, 17, 67 and 68 were previously pending. Applicants amended claims 1, 67 and 68, and added new claims 69-72. Claims 1-14, 17 and 67-72 are pending and will be examined.
- 3. Applicants' amendments did not overcome any of the previously presented rejections. Applicants' arguments are addressed in the "Response to Arguments" section below.

Response to Arguments

- Applicant's arguments filed August 2, 2005 have been fully considered but they are not 4. persuasive.
- A) Regarding the rejection of claims 1-6, 17, 67 and 68 under 35 U.S.C. 103(a) over Kallioniemi et al. and McGill et al., Applicants argue that there is no suggestion in either Kallioniemi et al. or McGill et al. as to a CGH hybridization method in which using small target nucleic acid fragments results in less aggregating hybridization or less background. Applicants further argue that neither Kallioniemi et al. nor McGill et al. suggest using short probes comprising nucleic acids from one or more chromosomes of an organism, making claim 72 and dependent claims 67-69 unobvious over the references.

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B) Regarding the rejection of claims 7, 8 and 10 under 35 U.S.C. 103(a) over Kallioniemi et al. and McGill et al. in view of Anderson et al., Applicants argue that since claim 1 is not obvious over Kallioniemi et al. and McGill et al., this rejection is improper.

- C) Regarding the rejection of claim 9 under 35 U.S.C. 103(a) over Kallioniemi et al. and McGill et al. in view of Anderson et al. and Waggoner, Applicants argue that since claim 1 is not obvious over Kallioniemi et al. and McGill et al., this rejection is improper.
- D) Regarding the rejection of claim 11 under 35 U.S.C. 103(a) over Kallioniemi et al. and McGill et al. in view of Anderson et al. and Ordahl et al., Applicants argue that since claim 1 is not obvious over Kallioniemi et al. and McGill et al., this rejection is improper.

Regarding A), the newly introduced limitation of the method resulting in less aggregating hybridization or less background when probes of less than 200 bp are used is just that, a result of performing the method steps (a)-(c). Therefore, since the combined references of Kallioniemi et al. and McGill et al. teach using probes of 20 bp, which are shorter than 200 bp, the result of performing their method will also be reduced probe aggregation and lower background. Further, it is also inherent in the size of the 20 bp probe, which appears every 1,099,511,627,776 bp in the genome (as compared to human genome size of 3,000,000,000 bp), that binding of such probes will be very specific, therefore reducing background and non-specific aggregation.

Regarding the fact that claim 72 is not suggested by either reference, Kallioniemi et al. teach sample DNA containing all of the DNA from a tissue (page 14, [0152] and page 15, [0156]), therefore, they suggest target samples with complexities required by claims 72 and 67-69.

The rejection is maintained.

Regarding B)-D), the arguments concerning rejection of claim 1 over the combination of Kallioniemi et al. and McGill et al. are addressed above.

The rejections are maintained.

Claim Objections

5. Claim 69 is objected to because of the following informalities: there is no period at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 7. Claims 1-14, 17 and 67-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- A) Claims 1-14, 17 and 67-72 are indefinite in claim 1. Claim 1 is indefinite over the recitation of "greater than about 50 kilobases" (line 8), "smaller than about 200 bases" (line 12) and "greater than about 200 bases" (lines 19 and 21/22). It is vague and indefinite what is meant by the phrase "greater than about 50 kilobases" or "greater than about 200 bases". The phrase "greater than" typically indicates a minimum point. The phrase "greater than" however, is contraverted by the term "about" which implies that values above and below 50 kilobases or 200 bases are permitted. Further, the extent of variance permitted by "about" is unclear in this context. Since nucleotides are whole numbers, "about 200" cannot mean from 198.5 to 210.4 because nucleotides cannot be split into smaller parts. Therefore, it is also unclear if "about 200" simply includes 198 or if it also includes 1-197 as well, for example. Similarly, the phrase "smaller than" indicates a maximum value, however, the term "about" implies values above and below that maximum value, making the phrase "smaller than about" indefinite.

B) Claims 2-5 are indefinite over the recitation of "no more than about X bases", with X being 150, 100, 50 or 30. The phrase "no more than" indicates a maximum value, for example, 150 bases, however, the term "about" implies values above and below that maximum value, making the phrase "no more than about" indefinite.

Claim Interpretation

- Applicants did not define the term "about X bases", therefore, for example, the term "about 30 bases" is interpreted as any number of bases between one and 100, for example. In addition, the phrase "greater than about X bases" is interpreted as any number of bases, as are phrases "smaller than about X bases" and "no more than about X bases".
- 9. With respect to the term "stringent hybridization conditions", Applicants provided the following description (page 13, lines 14-19 and 29-31; page 14, line 1):
 - "...The term "stringent conditions" refers to conditions under which a probe will hybridize preferentially to its target subsequence, and to a lesser extent to, or not at all to, other sequences. A "stringent hybridization" and "stringent hybridization wash conditions" in the context of nucleic acid hybridization (e.g., as in array, Southern or Northern hybridizations) are sequence dependent, and are different under different environmental parameters." And "...However, the selection of a hybridization format is not critical, as is known in the art, it is the stringency of the wash conditions that set forth the conditions which determine whether a nucleic acid is within the scope of the invention."

Therefore, depending on the length of the nucleic acids participating in the hybridization reaction, different conditions will be considered as being "stringent".

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 11. Claims 1-6, 12, 13, 70 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Cai et al. (Genomics, vol. 54, pp. 387-397, 1998).

Regarding claim 1, 70 and 71, Cai et al. teach a method for generating a molecular profile of genomic DNA by hybridization of target nucleic acids to an array of plurality of immobilized probes by the method comprising:

- (a) providing the plurality of nucleic acid probes comprising a plurality of immobilized nucleic acid segments in an array with each probe at a known location, wherein each probe is a member of a genomic library cloned in a vector, and each probe is the vector having a cloned nucleic acid insert greater than about 50 kilobases, wherein the plurality of probes represents all of the chromosome or a genome (Cai et al. teach BAC arrays of mouse genome on DNA filters (page 388, third paragraph; Fig. 1 and 2). Cai et al. teach an array of clones representing all of the mouse genome (388, third paragraph). Cai et al. teach an array of BAC clones each of which has an insert of average size of about 196 kb, which anticipates the limitation of an average insert size of greater than about 50 kb (388, third paragraph). Cai et al. teach an array of clones at known locations (Fig. 1 and 2).);
- (b) contacting the immobilized probes with a sample of target nucleic acid comprising fragments of genomic nucleic acid labeled with a detectable moiety, wherein each labeled fragment consists of a length smaller than about 200 bases, and the contacting is under conditions allowing

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hybridization of the target nucleic acid to the probe nucleic acid (Cai et al. teach labeled oligonucleotides amplified from target genomic DNA by PCR (page 388, paragraphs 4-6). The oligonucleotides (= target DNA) are contacted with the immobilized probes under conditions which permits hybridization of the target to the probes (page 388, last paragraph). Cai et al. teach oligonucleotides of 50 bp, anticipating the limitation of lengths smaller than about 200 bp (page 391, second paragraph).); and

(c) observing an amount and location of labeled genomic nucleic acid hybridized to each immobilized probe, to detect regions of amplification or deletion in the sample, wherein positional information of clones on the arrays and chromosomes is correlated, thereby generating a molecular profile of the chromosome or genome of the sample genomic nucleic acid (Cai et al. teach observation of hybridization events by exposing X-ray films to the hybridization membranes and examining the autoradiograms (page 389, first paragraph; Fig. 2). Cai et al. teach correlation of positional information of clones on the array and chromosomes (page 389, fifth and last paragraphs). Cai et al. do not specifically teach determination of regions of amplification or deletion in the sample, but that is inherent in that they perform the method steps claimed.),

wherein said method results in less aggregating hybridization to said probes relative to hybridization of said target genomic nucleic acid to said probes using target nucleic acids with labeled fragments of length greater than about 200 bases,

or said method results in less background relative to hybridization of said target genomic nucleic acid using target nucleic acids with labeled fragments of length greater than about 200 bases (Cai et al. teach hybridization of the probes resulting in low background (page 391, first paragraph). Further, since only two probes were used for each chromosome, this would result in less aggregation of the probes during hybridization).

Regarding claims 2-6, Cai et al. teach oligonucleotides of 40-50 bp long (page 391, second paragraph; page 395, first paragraph), anticipating the limitations of fragments no more than about 150 bases long, no more than about 100 bases long, no more than about 50 bases long, no more than about 30 bases long and fragments with length between about 30 bases and about 150 bases.

Regarding claims 12 and 13, Cai et al. teach stringent hybridization conditions of 65 °C (page 388, last paragraph).

Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. Claims 1-6, 12-14, 17 and 67-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kallioniemi et al. (US 2002/0132246 A1; cited in the previous office action), McGill et al. (US 5,658,730 A; cited in the previous office action) and Pollack et al. (Nature Genetics, vol. 23, pp. 41-46, September 1999).
- A) Regarding claim 1, Kallioniemi et al. teach detection gene copy number amplifications or deletions by hybridization of target nucleic acids to an array of plurality of immobilized probes by the method comprising:
- (a) providing the plurality of nucleic acid probes comprising a plurality of immobilized nucleic acid segments in an array with each probe at a known location, wherein each probe is a member of a genomic library cloned in a vector, and each probe is the vector having a cloned nucleic acid insert greater than about 50 kilobases, wherein the plurality of probes represents all of the chromosome or a genome (Kallioniemi et al. teach CGH (comparative genomic hybridization)

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arrays (page 2, [0013], [0022]), and DNA arrays in which large-insert genomic clones such as P1, BAC or PAC clones are attached to solid support (page 3, 4 [0053]). Kallioniemi et al. teach an array of clones representing all of the human genome (page 14, [0152], [0153]). Kallioniemi et al. teach an array of P1, BAC or PAC clones each of which has an insert of 80 to 150 kilobases (page

15, [0156]). Kallioniemi et al. teach an array of clones at known locations (Fig. 14).);

(b) contacting the immobilized probes with a sample of target nucleic acid comprising fragments of genomic nucleic acid labeled with a detectable moiety, wherein each labeled fragment consists of a length smaller than about 200 bases, and the contacting is under conditions allowing hybridization of the target nucleic acid to the probe nucleic acid (Kallioniemi et al. teach contacting genomic DNA target labeled with a fluorescent dye (= detectable moiety) to a CGH array (page 14, [0152]). The target DNA is contacted with the immobilized probes under conditions which permitted hybridization of the target to the probes (page 2, [0016]).); and

(c) observing an amount and location of labeled genomic nucleic acid hybridized to each immobilized probe, to detect regions of amplification or deletion in the sample, wherein positional information of clones on the arrays and chromosomes is correlated, thereby generating a molecular profile of the chromosome or genome of the sample genomic nucleic acid (Kallioniemi et al. teach observation of hybridization events using a CCD camera and detection gene amplifications or deletions on chromosomes (page 2, [0013], [0016]; page 15 [0157], [0160]).)

Regarding claims 12 and 13, Kallioniemi et al. teach hybridization conditions of 42° C and wash of 55° C (page 8, 9, [0100], therefore, according to Applicants' description, they teach stringent hybridization conditions and temperature about 60° C.

Regarding claim 14, Kallioniemi et al. teach target nucleic acid consisting of human DNA (page 14, [0152]).

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Regarding claim 17, Kallioniemi et al. teach human genome (page 14, [0153]).

Regarding claims 67 and 72, Kallioniemi et al. teach the sample nucleic acid being chromosome 22 (page 10, [0116]).

Regarding claims 68 and 72, Kallioniemi et al. teach the sample nucleic acid being total human DNA, therefore anticipating the limitations of a sample comprising at least one chromosome and a sample comprising a complete genome (page 14, [0152]; page 15, [0156]).

Regarding claim 69, Kallioniemi et al. teach human genome (page 14, [0153]). Therefore, since human genome contains at least 30% of repetitive sequences, by teaching human genome Kallioniemi et al. inherently anticipate this limitation.

- B) Kallioniemi et al. do not teach DNA fragments with length of less than about 200 bp to less than about 30 bp.
- C) Regarding claims 1-6, 70 and 71, McGill et al. teach detection of chromosome 8 amplification using probes derived from the chromosome (col. 3, lines 56-67; col. 4, lines 16). The probe lengths were 10-500 bp (col. 5, lines 35-45 and 52-55), with the optimal probe sequence being about 20 bases (col. 6, lines 1-10). Therefore, since the probes of McGill et al. are shorter than 200 bp, the result of using them in hybridization would be less probe aggregation and lower hybridization background, since each of the probes would anneal to a 20 bp sequence which appears once in 4²⁰ bp in the genome, or once every 1,099,511,627,776 bp in the genome (as compared to human genome size of 3,000,000,000 bp), that binding of such probes will be very specific, therefore reducing background and non-specific aggregation.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used short probes of McGill et al. in the hybridization method of Kallioniemi et

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al. The motivation to do so, provided by McGill et al., would have been that probes with about 20 bases allows formation of duplexes which are stable and selective (col. 6, lines 1-3).

Additional motivation for using short probes is provided by Pollack et al., who teach hybridization of DpnII digested and labeled genomic DNAs to cDNA arrays (Abstract; page 46, first paragraph). They found that reducing the size of genomic DNA before labeling improved labeling efficiency by providing greater accessibility of the DNA template following digestion. Such greater accessibility would also allow more specific annealing of the probes to the array.

- Claims 7, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kallioniemi et al. (US 2002/0132246 A1; cited in the previous office action), McGill et al. (US 5,658,730 A; cited in the previous office action) and Pollack et al. (Nature Genetics, vol. 23, pp. 41-46, September 1999)as applied to claim 1 above, and further in view of Anderson (Nucl. Acids Res., vol. 9, pp. 3015-3027, 1991; cited in the previous office action).
- A) Regarding claim 7, Kallioniemi et al. teach generation of nucleic acids by polymerase chain reaction, nick translation or random priming (page 10, [0114]-[0116].

Regarding claim 8, Kallioniemi et al. teach labeling of nucleic acid fragments by nick translation or random priming (page 10, [0116]).

- B) Neither Kallioniemi et al. nor McGill et al. teach fractionation of DNA by DNAse digestion.
- C) Anderson teaches fragmentation of genomic DNA to sizes below 200 base pairs by digestion with 2.2 ng or more of DNAse I (Figure 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used DNAse I digestion of Anderson to fragment genomic target DNA in the method of Kallioniemi et al. and McGill et al. The motivation to do so, provided by Anderson,

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would have been that DNAse I digestion was sequence-independent and the sizes distribution obtained could be regulated by regulating the amount of DNAse I in the reaction (page 3019, first two paragraphs).

- Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kallioniemi et al. (US 2002/0132246 A1; cited in the previous office action), McGill et al. (US 5,658,730 A; cited in the previous office action) and Pollack et al. (Nature Genetics, vol. 23, pp. 41-46, September 1999), in view of Anderson (Nucl. Acids Res., vol. 9, pp. 3015-3027, 1991; cited in the previous office action), as applied to claim 8 above, and further in view of Waggoner et al. (U. S. Patent No. 5,268,486; cited in the previous office action).
 - A) Claim 9 is drawn to the label comprising Cy3 or Cy5.
 - B) Kallioniemi et al. and McGill et al. teach fluorescent labels, but do not teach Cy3 or Cy5.
- C) Waggoner et al. teach luminescent cyanine dyes, including Cy3 and Cy 5 (col. 19, formula at the bottom; claim 8; Cy3 has m=1, Cy5 has m=2). The dyes are be used to label nucleic acids (col. 2, lines 58-61; col. 4, lines 29-35).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the cyanine dyes of Waggoner et al. in the method of Kallioniemi et al. and McGill et al. The motivation to do so, provided by Waggoner et al., would have been that cyanine dyes were used for detecting mixtures of components because they had a wide range of excitation and emission wavelengths (col. 4, lines 36-49).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kallioniemi et al. (US 2002/0132246 A1; cited in the previous office action), McGill et al. (US 5,658,730 A; cited in the previous office action) and Pollack et al. (Nature Genetics, vol. 23, pp. 41-46, September 1999), as applied to claim 1 above, and further in view of Ordahl et al. (Nucl. Acids Res., vol. 3, pp. 2985-

2999, 1976; cited in the previous office action) and Anderson (Nucl. Acids Res., vol. 9, pp. 3015-3027, 1981; cited in the previous office action).

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- A) Claim 11 is drawn to fragmentation of genomic DNA to sizes smaller than 200 bases by applying shear forces to fragment genomic DNA followed DNAse digestion.
- B) Neither Kallioniemi et al. nor McGill et al. teach fragmentation of genomic DNA to sizes smaller than 200 bases by applying shear forces to fragment genomic DNA followed DNAse digestion.
- C) Ordahl et al. teach fragmentation of genomic DNA in preparation for DNA hybridization experiments. Ordahl et al. teach that it is advantageous to use DNA fragments of less than 500 bp in hybridization experiments (page 2985, first paragraph). Ordahl et al. teach that DNA fragmented in French press had an average size of 230 base pairs (Abstract; page 2986; Fig. 4). Ordahl et al. do not teach DNAse I fragmentation after shearing.
- D) Anderson teaches fragmentation of genomic DNA to sizes below 200 base pairs by digestion with 2.2 ng or more of DNAse I (Figure 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used shearing of Ordahl et al. and DNAse I digestion of Anderson to fragment genomic target DNA in the method of Kallioniemi et al. and McGill et al. The motivation to do so, provided by Ordahl et al. and Anderson, would have been that it was advantageous to use short DNA fragments in hybridization (Ordahl, p. 2885, first paragraph) and that DNAse I digestion was sequence-independent and the sizes distribution obtained could be regulated by regulating the amount of DNAse I in the reaction (Anderson, page 3019, first two paragraphs).

17. No claims are allowed.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 12, 2005

TERESA STRZELECKA
PATENT EXAMINER
Teresa Structucy